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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,725

10/19/2004

Toshiro Omori

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38834

7590

11/13/2008

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,725	Applicant(s) OMORI ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 07/28/2008 with the amendment of claim 27 and newly added claim 30.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1-30 are currently pending.

The election/restriction requirement inadvertently mailed out on 09/24/2007 has been withdrawn. However, the original election/restriction requirement mailed out on 04/14/2006 still stands.

This application contains claims 8-26 drawn to an invention nonelected without traverse in the reply filed on 12 May 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-7 and newly added claims 27-30 are currently under examination.

Response to Amendment

Claim Rejections - 35 USC § 102

Claims 1-7, 28 and 29 are rejected and newly amended claim 27 and new claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Omori et al. (N*). Partially

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newly applied as necessitated by the amendment of claim 27 and newly added claim 30.

This rejection is maintained for reasons of record set forth in the paper mailed on 03/26/2008 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 07/28/2008.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Omori teaches a method of obtaining a composition by subjecting residual liquid by-produced in the shochu-production using barley as a raw material and obtained by distilling the shochu to a solid-liquid separation to provide a liquid component, filtering the obtained liquid component to provide a clear liquid, concentrating the obtained clear liquid to provide a concentrated liquid, subjecting the concentrated liquid to absorption treatment by using a synthetic absorbent to provide an unabsorbed (non-adsorbed) fraction, and drying the obtained unabsorbed (non-adsorbed) fraction (See abstract and paragraph 0001). Omori teaches that the synthetic absorbent can be an aromatic system synthetic material or a methacrylic synthetic adsorbent material (See claim 5). Omori further teaches that freeze drying is a suitable method of drying the non-adsorbed fraction (See paragraph 0014).

Although Omori does not teach that the composition obtained by solid/liquid separation of shochu stillage contains the components claimed by Applicant nor does Omori teach that the composition is a pharmaceutical nor does Omori teach that the

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composition obtained is capable of treating or preventing the onset of alcoholic hepatopathy in a patient in need thereof; however, the method of making the composition taught Omori is one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the composition obtained by solid/liquid separation of shochu stillage taught by Omori, which recites the same method steps as claimed by Applicant to provide a product-by-process, inherently contains the components in the ranges claimed by Applicant, is inherently a pharmaceutical composition and inherently displays the properties claimed by Applicant.

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that Omori teaches a condensation step that is not present in Applicant's invention and that if a synthetic absorbent process is conducted here, the composition of the composition matter that absorbs and the composition of the composition matter that pass through would differ because of the difference in the concentration of the liquid passing through.

However, this is not found persuasive because although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Applicant's claims do not recite the limitation that a condensation step does not occur. The way the claims are currently written, the Omori reference teaches the instantly claimed method steps of subjecting barley shochu stillage, obtained by the production of shochu from barley (*Hordeum vulgare* L.) as a raw material, to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation

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treatment by adsorption using a synthetic adsorbent, where unadsorbed product of said separation treatment is said composition. At present, the claims do not indicate a materially different product than that taught by Omori.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
November 3, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655